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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,202	01/23/2002	M. Reza Movahed	Q055	8365

7590

10/14/2003

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EXAMINER
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SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/14/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/057,202

Applicant(s)

MOVAHED, M. REZA

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2002 and 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is /closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-22, 27-29, 31-37, 42-47 and 49-53 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 7, 23-26, 30, 38-41, 48 and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 and 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities: On page 12 line 14, it appears that "3" should be --30--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3 and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Reich.

Regarding claims 1, 3, 44, 46 and 47, Reich teaches an apparatus for preventing contrast associated nephropathy by using a balloon tipped catheter (10) and suctioning the contrast from orifice (14) to filtration system (17) during specified times (col. 3 lines 57-61). Reich also discloses that a specially shaped catheter may be used (see figure 5 and col. 4 lines 64-67).

Regarding claims 2 and 45, Reich discloses a method for preventing contrast associated nephropathy by inflating a balloon tipped catheter (10) to form an occlusion to retain contrast upstream of said occlusion and removing the contrast through orifice (14) for a predetermined amount of time. See col. 3 line 66 – col. 4 line 4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6 and 9-14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reich.

Webster's II New Riverside University Dictionary (1994) defines *pump* as a "device or machine for transferring a gas or liquid from a source or container through tubes or pipes to another container or receiver."

Regarding claims 6 and 9-14, although Reich teaches controlled drainage flow rates (col. 3 lines 25-30) and timed coordination of inflation/deflation of the balloon to injection of contrast (col. 3 line 54 – col. 4 line 4), Reich does not explicitly discuss first and second pumps. It is inherent however, that increasing/decreasing the drainage flow rate and inflation/deflation of the balloon would require respective pumps to effect controlled transfer of blood/contrast agent from orifice (14) to the filter and air from inflation device (18) to balloon (and vice versa) in short amounts of time. Alternatively, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to use inflation/deflation and suction pumps in the invention as taught by Reich to provide an effective means for controllably transferring blood/contrast agent from orifice (14) to the filter and air from inflation device (18) to balloon (and vice versa). Furthermore, lacking any criticality, the timing of inflation to the injection of contrast

agent would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular patient and contrast used without undue experimentation.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Aldea of record.

Regarding claim 8, although Reich discloses pressure monitoring capabilities (col. 3 lines 25-30), Reich differs from the claimed invention in that a distal sensor is not explicitly addressed. Aldea teaches a coronary sinus reperfusion catheter having a distal pressure sensor providing control signals (col. 6 line 61 – col. 7 line 15). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to employ a distal sensor as taught by Aldea in the invention as taught by Reich to provide faster and more accurate readings of blood flow in the area being treated.

4. Claims 15, 16, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich.

Regarding claims 15, 16, 49 and 50, although Reich teaches that a specially shaped catheter may be used, Reich does not explicitly address a C- or S- shaped bend. However, lacking any criticality, the shape of catheter used would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular configuration of the patient without undue experimentation.

5. Claims 17-19, 27-29, 31-37, 42, 43, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Sterman et al. (WO 99/33407) of record.

Regarding claims 17-19, 27-29, 31-33, 36, 37, 42, 43, 51 and 52, Reich teaches all of the claimed subject matter except that injection of the contrast agent using a second catheter is not addressed. Sterman et al. provides the general teaching of using two catheters for the isolated injection and retrieval of a therapeutic agent or contrast agent. See p. 3 lines 7-24, p. 6 lines 7-12, and p. 8 lines 1-10. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to utilize a second catheter as taught by Sterman et al. for injecting the contrast agent in Reich to provide controlled administration of the agent in the region of interest with minimum or no loss of the agent into systemic circulation. Furthermore, lacking any criticality, the timing of inflation to the injection of contrast agent as well as amount of filtration would have been obvious matters of design choice to a person of ordinary skill in the art depending upon the particular patient and procedure performed without undue experimentation. Further regarding claims 34 and 35, Reich does not explicitly address a C- or S- shaped bend. However, lacking any criticality, the type of specially shaped catheter used would have been an obvious matter of design choice to a person of ordinary skill in the art depending upon the particular configuration of the patient without undue experimentation.

6. Claims 20-22 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Sterman et al. (WO 99/33407) of record and further in view of Aldea of record.

Regarding claims 20-22 and 53, although Reich discloses pressure monitoring capabilities (col. 3 lines 25-30), Reich and Sterman et al. differ from the claimed

invention in that a distal sensor is not explicitly addressed. Aldea teaches a coronary sinus reperfusion catheter having a distal pressure sensor providing control signals (col. 6 line 61 – col. 7 line 15). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to employ a distal sensor as taught by Aldea in the invention as taught by Reich in view of Sterman et al. to provide faster and more accurate readings of blood flow in the area being treated.

***Allowable Subject Matter***

7. Claims 4, 5, 7, 23-26, 30, 38-41, 48 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cambron et al. (6,537,495) teaches controlling the venous flow rate using a pump (col. 12 lines 14-20).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

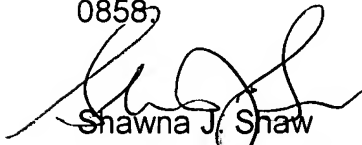
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

0858

A handwritten signature in black ink, appearing to read 'Shawna J. Shaw', is written over the printed name.

Shawna J. Shaw  
Primary Examiner  
10/9/03